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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,741	Applicant(s) SAUER ET AL.	
	Examiner Brent Page	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-44 is/are pending in the application.
- 4a) Of the above claim(s) 22-24, 29-34, 37-39 and 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21, 25-28, 35, 36, 40 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV and SEQ ID NO: 11 in the reply filed on 06/28/2007 is acknowledged. The traversal is on the ground(s) that there is unity between the groups. This is not found persuasive because the special technical feature of an ESPS promoter was taught in the art, and because each group contains a unique sequence ID NO:, wherein a search for any one of these SEQ ID NOs would be insufficient for the search of any other Seq ID No:. Furthermore, Applicants argue that there is no undue search burden. This is not persuasive because of the resources now required to search each individual sequence are limited as sequence databases continue to grow larger.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-44 are pending with Claims 22-24, 29-34, 37-39 and 41-43 withdrawn as non-elected subject matter. Claims 19-21, 25-28, 35-36, 40 and 44 are examined on the merits in the office action below.

Claim Objections

Claims 19-21, 25-28, 35-36, 40 and 44 are objected to because of the following informalities: The claims contain non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21, 25-28, 35-36, 40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method for expression of one or more genes in a plant of the genus *Tagetes* comprising utilizing any CHRC promoter from any species wherein the expression takes place specifically in flower petals. The claims encompass any CHRC promoter in addition to embodiments that comprise "a" nucleic acid sequence of SEQ ID NO: 11, wherein "a" sequence could mean as little as 2 base pair, as well as a sequence "derived" from these sequences by substitution, insertion or deletion of nucleotides, as well as sequences that merely hybridize under unspecified stringency conditions to SEQ ID NO: 11.

In contrast, the specification only gives guidance to make and use the promoter defined by SEQ ID NO:11 or SEQ ID NO: 12 or SEQ ID NO:13 or SEQ ID NO:14. No guidance is provided for making and using any other promoters or promoter-effective DNA molecules that would specifically express heterologous genes in the flower petals of *Tagetes* as broadly claimed. There are literally millions of embodiments based on the claim language, where a vast majority would be inoperable.

The function of promoter fragments and sequence variants in transgenic plants is unpredictable. Kim et al (1994, Plant Molecular Biology 24:105-117) in a mutational analysis of the nopaline synthase promoter in a stable transformation system, found that mutation of a single nucleotide significantly altered the strength of expression, while deletions in other regions of the promoter completely eliminated function (page 108 first full paragraph).

Deletion analysis of promoters is unpredictable. McDonald et al (1990, EMBO J. 9:1717-1726) teach that a crucial promoter element for the *Arabidopsis* rcbS-1A promoter is located in the region about 250 bases upstream of the transcription initiation site.

Furthermore, the function of promoter fragments and sequence variants in transgenic plants is unpredictable wherein the promoter function is regulated by conditional elements. Dolferus et al (1994, Plant Physiology 105:1075-1087) in a deletion analysis of the *Arabidopsis* *Adh* promoter, found that deletion of different elements of the promoter affected promoter function conditional to the stress that was applied to the given promoter fragment (page 1080, last full paragraph and page 1082 first full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate all promoter-effective molecules that would give floral specific expression in *Tagetes* as broadly claimed.

Claims 19-21, 25-28, 35-36, 40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for expression of one or more genes in a plant of the genus *Tagetes* comprising utilizing any CHRC promoter from any species wherein the expression takes place specifically in flower petals. The claims encompass any CHRC promoter in addition to embodiments that comprise "a" nucleic acid sequence of SEQ ID NO: 11, wherein "a" sequence could mean as little as 2 base pair, as well as a sequence "derived" from these sequences by substitution, insertion or deletion of nucleotides, as well as sequences that merely hybridize under unspecified stringency conditions to SEQ ID NO: 11.

In contrast, the specification only describes SEQ ID NO:11 or SEQ ID NO: 12 or SEQ ID NO:13 or SEQ ID NO:14. No description is provided for any of the other of literally millions of sequences. Furthermore no particular structures are described which particularly give the function of petal-specific driven expression.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The

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court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences

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as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21, 25-28, 35-36, 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauptmann et al (US Patent 7223909, filed in the US on March 20th 2003) in view of Vishnevetsky et al (November, 1999 The Plant Journal 20:423-431).

The claims are broadly drawn to a method for expression of one or more genes in a plant of the genus *Tagetes* comprising utilizing any CHRC promoter from any species wherein the expression takes place specifically in flower petals, wherein the expressed genes are not expressed in wild-type plants of the genus *Tagetes* as well as a genetically modified plant from said method.

Hauptmann et al teach a transgenic *Tagetes erecta* transformed with a transgene that encodes a chimeric ketolase enzyme from bacteria, wherein the promoter that controls expression is a flower-preferred promoter (see claims 1, 10 and 15, as well as paragraphs 74 and 114) wherein the method of expression one or more genes is described in the specification.

Hauptmann et al do not teach the CHRC promoter.

Vishnevetsky et al teach the CHRC promoter as well as the flower petal specificity of the promoter (see abstract, page 425 bottom of first column, for example).

It would have been obvious to one of ordinary skill in the art to modify the method and plant taught by Hauptmann et al, by using the promoter taught by Vishnevetsky as suggested by Hauptmann et al when suggesting the use of flower-specific promoters (Paragraph 114 of specification). Furthermore, the direct link of the CHRC promoter to carotenoid accumulation as taught by Vishnevetsky and the carotenoid accumulation taught by Hauptmann et al would render it obvious and provides motivation to use the CHRC promoter for carotenoid accumulation in marigold as taught by Hauptmann et al.; and that one of ordinary skill in the art would have a reasonable expectation of success.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER

Russell P. Kallis